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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,965	05/10/2006	Markus Luy	2024.5	8557
7590 07/29/2009				
Scott E Hanf Hammer & Hanf Suite G 3125 Springbank Lane Charlotte, NC 28226			EXAMINER AFREMOVA, VERA	
			ART UNIT 1657	PAPER NUMBER
			MAIL DATE 07/29/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/578,965

Applicant(s)

LUY ET AL.

Examiner

Vera Afremova

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 14-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/07/2009 has been entered.

Claims 1-13 are under examination in the instant office action.

This application contains claims 14-20 drawn to invention(s) nonelected with traverse in the reply filed on 5/06/2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,582,941 (Yokochi et al), US 6,509,178 (Tanaka et al), EP 0 113 183 (IDS reference) and Bajpai et al. (IDS reference).

Claims are directed to methods for cultivating microorganisms belonging to *Thraustochytriales* wherein the method comprise step of cultivating microorganisms belonging

to *Thraustochytriales* in a fermentation medium comprising calcium carbonate in amounts 3-15 g/L as means for pH control. The claimed cultivation method is intended for production of oils, DHA and DPA. Some claims are further drawn to cultivation conditions such as pH 3-10, temperature between 10 and 40 degree C and cultivation time 1-10 days. Some claims are further drawn to the use of fermentation medium comprising glucose, corn steep liquor, potassium hydrogen phosphate, ammonium sulfate, magnesium and calcium chloride, calcium carbonate and sodium sulfate. Some claims are further drawn to culturing microorganisms belonging to *Thraustochytriales* such as *Schizochytrium sp.* strain SR21 and *Ulkenia sp.* strain SAM 2179.

US 6,582,941 (Yokochi et al) and US 6,509,178 (Tanaka et al) teach methods for cultivation of microorganisms belonging to *Thraustochytriales* as intended for production of DHA and DPA. The cited methods include cultivation of the *Thraustochytriales* representatives such as *Schizochytrium sp.* strain SR21 (US 6,582,941 at abstract and table 7) and *Ulkenia sp.* strain SAM 2179 (US 6,509,178 at abstract and table 1). The disclosed cultivation conditions are within the presently claimed ranges of cultivation conditions that they include pH 4-6.5 temperature between 10 and 35 degree C and cultivation time 3-7 days. The disclosed fermentation media contain same nutrients as required by the claimed invention including glucose, corn steep liquor, potassium hydrogen phosphate, ammonium sulfate and sea salts that comprise magnesium and calcium chloride, calcium carbonate and sodium sulfate at least to some extent. For example: see US 6,582,941 at col. 10, lines 66-67; col.11, lines 1-3; col.18, lines 14-20. For example: see US 6,509,178 at col. 7, lines 50-57; col. 8, lines 1-14.

The method of the cited patents result in accumulation or production of more than 10% DHA per biomass weigh and more than 1 % of DPA per biomass weigh. For example: US

6,582,941 discloses accumulation or production by SR21 strain of more than 10% DHA per weigh or about 17 % (table 7; 54% total fat per weight and 34 % DHA per total fat). The cited US 6,509,178 also discloses accumulation or production by SAM 2179 strain of more than 10% DHA per weigh and more than 1 % DPA (table 1).

The cited patents US 6,582,941 (Yokochi et al) and US 6,509,178 (Tanaka et al) teach pH control during cultivation of microorganisms belonging to *Thraustochytriales* but the cited references only disclose the use of a generic suitable acid and/or base material, thus, being silent about calcium carbonate as material for pH adjustments.

However, EP 0 113 183 teaches the pH control during microbial cultivation with pH controlling material such as calcium carbonate (see abstract) including concentrations 0.5-5 g/L in fermentation medium (page 9, lines 9-11). Further, the reference by Bajpai et al. teaches cultivation of microbial representatives of *Thraustochytriales* in a fermentation medium with calcium carbonate (at "materials and methods" and Fig. 1).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use calcium carbonate as pH controlling material during cultivation of microorganisms belonging to *Thraustochytriales* with a reasonable expectation of success in culturing the microorganisms belonging to *Thraustochytriales* because the prior art prior art teaches the use of calcium carbonate as pH controlling material as adequately taught by EP 0 113 183 and because microorganisms belonging to *Thraustochytriales* have been cultured in the presence of calcium carbonate as intended for oils, DHA and DPA production as evidenced by Bajpai et al. The claimed specific strains SR 21 and SAM 2179 have been known

and cultured in the fermentation methods as intended for oils, DHA and DPA production as adequately demonstrated by US 6,582,941 (Yokochi et al) and US 6,509,178 (Tanaka et al).

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references.

Therefore, the claims are properly rejected under 35 USC § 103.

Response to Arguments

Applicant's arguments filed 5/07/2009 have been fully considered but they are not persuasive.

With regard to claim rejection under 35 USC § 103 applicants argue that there is no suggestion or motivation to combine or modify the teaching of the cited references (response pages 7-11, for example). However, the cited references are in the same field of endeavor (such as culturing microorganism at optimal pH and conditions) and they seek to solve the same problems as the instant application and claims (such as optimization of microbial culturing processes as intended for manufacturing of edible products), and one of skill in the art is free to select and/or to modify components available in the prior art, *In re Winslow*, 151 USPQ 48 (CCPA, 1966).

Although examiner recognizes that references cannot be arbitrarily combined that there must be some reason why one skilled in the art would be motivated to make the proposed combination of primary and secondary references, *In re Nomiya*, 184 USPQ 607 (CCPA 1975).

However, there is no requirement that a motivation to make the modification be expressly articulated. One test for combining references is what the combination of disclosures taken as a whole would suggest to one versed in the art, rather than by their specific disclosures, *In re* Bozek, 163 USPQ 545 (CCPA 1969). In this case, the use of calcium carbonate as a pH control agent during cultivation/fermentation of microorganisms is known in the prior art as evidenced by the teaching of EP 0 113 183 and the microorganisms belonging to *Thraustochytriales* have been successfully cultured in the presence of calcium carbonate as intended for oils, DHA and DPA production as evidenced by Bajpai et al.

With regard to EP 0 113 183 Applicants argue (response pages 12-13) that the cited document teaches the use of calcium carbonate in fermentations of yeasts and that the yeasts belong to a different group of microbes than *Thraustochytriales*. This argument does not have any persuasive grounds because one of skill in the art would clearly recognize that culturing any and all groups of microbes would benefit from the use of optimal pH and the cited EP 0 113 183 explicitly teaches the use of calcium carbonate as pH controlling agent in microbial fermentations.

Further, with regard to Bajpai et al. Applicants argue that the cited document discloses the use of calcium carbonate for culturing *Thraustochytriales* at concentration lower than it is required by the instant claims and that the cited document demonstrates lower production of microbial biomass, oils and DHA than achieved by Applicants. This argument does not have any persuasive grounds because Bajpai et al. clearly demonstrate that the representatives of *Thraustochytriales* have been cultured in the prior art in the presence of calcium carbonate as intended for oils, DHA and DPA production and because the claimed invention is solely directed

to culturing *Thraustochytriales* and it does not require recovery of products as argued and/or intended.

Applicants' arguments as based on unexpected effects such as increase in biomass, oil and DHA production by *Thraustochytriales* microorganisms (response pages 13-16) have been fully considered but not found persuasive for the very least reasons the evidence necessary to overcome a prima facie case of obviousness must not only be clear and convincing, but must also be commensurate in scope with the claimed subject matter. The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980).

In the instant case, the unexpected results as argued are based on biomass, oil and DHA production by 2 strains that are strain *Ulkenia* sp. SAM 2179 (specification table 1) and strain *Schizochytrium* sp. SR 21 (specification table 5). Yet, the pending claims 1-10 and 13 are broadly directed culturing the microorganisms of the order of *Thraustochytriales* and none of the claims 1-13 require recovery of products as argued.

Further, with respect to the particular claims 11 and 12 that encompass the use of *Ulkenia* sp. SAM 2179 and strain *Schizochytrium* sp. SR 21 it is noted that these strains are known in the prior art and they were used in the fermentation methods for oils, DHA and DPA production as adequately demonstrated by US 6,582,941 (Yokochi et al) and US 6,509,178 (Tanaka et al). Moreover, the cited documents demonstrate biomass, oils and/or DHA production by these particular strains as presently recited in the pending claims 2, 3 and 4. For example: US

6,582,941 discloses accumulation or production by SR21 strain of more than 10% DHA per weigh or about 17 % (table 7; 54% total fat per weight and 34 % DHA per total fat). The cited US 6,509,178 also discloses accumulation or production by SAM 2179 strain of more than 10% DHA per weigh and more than 1 % DPA (table 1).

Thus, the scope of pending claims do not commensurate with the scope of showing as argued.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1657

July 24, 2009

/Vera Afremova/
Primary Examiner, Art Unit 1657

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